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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,094	02/04/2002	Om Reddy Gaddam	DRF 3.0-023	5807
45776	7590	06/15/2006	EXAMINER	
DR. REDDY'S LABORATORIES, INC. 200 SOMERSET CORPORATE BLVD SEVENTH FLOOR, BRIDGEWATER, NJ 08807-2862			BERCH, MARK L	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,094

Applicant(s)

GADDAM ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-10, 13, 14, 17, 18 and 64-120 is/are pending in the application.
4a) Of the above claim(s) 3-10, 64 and 65 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 13, 14, 17, 18 and 66-120 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/1/2006 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 13-14, 17-18, 66-69, 71-86, 91-95, 97-113, 115-120 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. What exactly is "Amino guanidine hydrogen carbonate"? Is it the case that a) a comma is missing after the "amino guanidine", or b) the reaction produce of the two is intended, perhaps amino guanidium carbonate. Note that aminoguanidine (as one word, not two) appears further on in the claim.

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2. The M choices are all inaccurate. M must be a cation, but the M choices are generally neutral, not cations. There are two exceptions. Metformin (sold under the name Glucophage®, Fortamet®, or Riomet®), an anti-diabetic drug, is itself a hydrochloride, i.e. is of the form of the bisguanidium hydrochloride. That is, it does have the cation form, but there is an extra Cl anion, so that the “Metformin” is again neutral. It is not at all clear if the Cl is intended at all in the metformin salts. The other example is hydrogen carbonate, which is an anion altogether. This is based on the assumption a) (see above) is the case, but if it is actually b), the same problem arises. Also, see discussion of the “hydrogen carbonate” below.
3. A dash must appear after the “t” when it stands for tertiary, which was not done in claim 67, 68.
4. In claims 13-14, the compound is combined with a solvate of what? Deletion is suggested.

Claims 1, 13-14, 17-18, 66-69, 71-86, 91-95, 97-113, 115-120 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention.

There is total confusion about the anion involved here. Examples 8, 24 and 39 all use the wording “hydrogen carbonate”, which is the HCO_3 mono-anion. The structural formula in each case shows the HCO_2 mono-anion, i.e. one fewer oxygen, which in fact the formate. One of these is clearly wrong (it is also possible that both are wrong). One of ordinary skill in the art cannot tell which one, the wording or the structural formula, is

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wrong, and hence neither can be considered enabled. If applicants disagree, they must show that one of ordinary skill in the art, looking at the specification, could have determined which choice was actually intended.

Claims 1, 13, 17-18, 91, 109 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for $p=1$, does not reasonably provide enablement for $p=2$. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The $p=2$ choice makes no sense. On the left is a monoanion, and therefore it cannot have a charge of -2 .

Claims 91-120 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other disorders, does not reasonably provide enablement for leptin resistance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The reasons have been given previously. Leptin resistance is a condition in which cells fail to respond to the leptin signal. This failure can in turn lead to other disorders such as obesity. But the fact that these compounds can be effective against a symptom does not imply that they are effective against a cause itself, when the symptom --- obesity --- can arise from many different causes. These compounds are PPAR- α or PPAR- γ agonists. There is no well established connection between such agonists and leptin resistance itself. Indeed, there is no pharmacological treatment for leptin resistance per se. The sole reference that applicants supply in this regard is Bruning. That reference makes no mention of either the condition of leptin resistance or of either PPAR- α or PPAR- γ .

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 69-70, 83-90, 96, 114, are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray and Das.

The references were discussed previously. These disclose assorted Na and K salts. These claims have Li, Mg and Ca salts. These are obvious variants not only because salts generally are taught (see e.g. Das, column 16, lines 59-60, which specifically name the Li, Mg and Ca salts). The utility is the same. In addition, Das at column 85, lines 11-16 discloses the K, Mg, Ca, Li, Na, arginine and lysine salt which is identical to the salt of claim 70, except that the claim 70 species is 5-ethyl, and the prior art compound is 5-methyl. However, the 5-ethyl feature is clearly taught by the reference, as is seen from other 5-ethyl compounds in the same column. In addition, it is obvious as a homolog. Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologue. As was stated in *In re Grose*, 201 USPQ 57, 63, "The known structural relationship between adjacent homologues, for example, supplies a chemical theory upon which a *prima facie* case of obviousness of a compound may rest." The homologue is expected to be preparable by the same method and

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to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methyl groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 247; *Ex parte Henkel*, 130 USPQ 474; *In re Jones*, 74 USPQ 152, 154; *In re Herr*, 134 USPQ 176; *Ex parte Dibella*, 157 USPQ 59; *In re Zickendraht*, 138 USPQ 22; *Ex Parte Fischer*, 96 USPQ 345; *In re Fauque*, 121 USPQ 425; *In re Druey*, 138 USPQ 39; *In re Bowers and Orr*, 149 USPQ 570; *In re Jones*, 65 USPQ 480. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness. As was stated directly in *THE GENERAL TIRE & RUBBER COMPANY v. JEFFERSON CHEMICAL COMPANY, INC.*, 182 USPQ 70 (1974): "If any structural change is obvious to one skilled in the art, a substitution of the next higher homolog would seem to be." Note also *In re Jones*, 21 USPQ2d 1942, which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to *prima facie* obviousness"; one of those listed is "adjacent homologues and structural isomers". Similar is *In re Schechter and LaForge*, 98 USPQ 144, 150, which states "a novel useful chemical compound which is homologous or isomeric with compounds of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compounds." Note also *In re Deuel* 34 USPQ2d 1210, 1214 which states, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have

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similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." See also MPEP 2144.09, second paragraph.

Claim Objections

Claims 69-70 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The claims have metal salts, arginine salt, a lysine salt and a free acid (next to last claim 70 salt), which are not provided for in claim 1. This can be fixed by making the claims independent, and by either removing the free acid, since the invention and use is drawn to the salts, not the free acid, or by adding the missing salt part.

The name of the last species on page 12 is garbled because some letters appear as superscripts.

Specification

Examples 8, 24 and 39 all have the discrepancy noted above. These must be deleted, or the matter resolved as noted above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663.

The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**Mark L. Berch
Primary Examiner
Art Unit 1624**

6/12/2006